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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,031	11/22/2000	Hannele Tolo	0365-0476P	4589
7590 01/07/2004 Birch Stewart Kolasch & Birch PO Box 747 Falls Church, VA 22040-0747			EXAMINER ANDRES, JANET L	
			ART UNIT 1646	PAPER NUMBER

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary

Application No.

09/701,031

Applicant(s)

TOLO ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-12 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 29 August 2003 is acknowledged. Claims 1-3, 5-12, and 16-21 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejection of claims 1-4, 11, 16, and 19 under 35 U.S.C. 102(a) and (e) as anticipated by U.S. patent 6,096,872 is withdrawn in response to Applicant's amendment to the claims specifying the amount of detergent and cancellation of claim 4.

3. The rejection of claims 13-15 under 35 U.S.C. 102(b) as anticipated by WO 96/11018 and US patent 5,173,415 is withdrawn in response to Applicant's cancellation of these claims.

4. The rejection of claims 9 and 10 under 35 U.S.C. 103(a) as unpatentable over the '872 patent in view of the Whatman catalogue is withdrawn in response to Applicant's amendment specifying the amount of detergent.

5. The rejection of claims 1-19 under 35 U.S.C. 103(a) as unpatentable over the '415 patent or over the '415 patent in view of the Whatman catalogue is withdrawn in response to Applicant's argument that the instant results were unexpected in light of the '415 patent.

6. The rejection of claims 1-19 under 35 U.S.C. 103(a) as unpatentable over U.S. patent 4,732,683 in view of U.S. patent 4,808,315 is withdrawn in response to Applicant's amendment specifying the amount of detergent.

Claim Rejections Maintained/New Grounds of Rejection

7. Claims 1-3, 5-12, and 16-21 are newly rejected under 35 U.S.C. 103(a) as unpatentable over the '683 patent in view of the '315 patent and further in view of U.S. patent 4,481,189 (Prince, 1984).

As set forth in the previous office actions, the '683 patent teaches that polysorbate 80 can be used to inactivate virus in interferon alpha preparations. The '315 patent teaches filters for virus removal. The '189 patent in more detail that polysorbate 80 at concentrations of .1 - 1.0 % (.1 - 1.0 g/L) (column 4, lines 34-47) can be used to inactivate viruses. Thus it would be obvious to one of ordinary skill in the art to combine treatment with polysorbate 80 at the concentrations specified by the instant claims, followed by filtration on a virus removal filter, to produce virus-free alpha interferon preparations. One of ordinary skill would be motivated to do so because the two steps have the same purpose, and it is thus *prima facie* obvious to combine them, as stated in the previous office actions.

Applicant has argued with respect to the rejection of the claims as unpatentable over the '683 patent in view of the '315 patent that the results are unexpected. Applicant additionally argues that the present invention is not based on virus inactivation by detergent, and that neither patent discloses that detergents prevent protein losses or clogging of filters.

Applicant's arguments have been fully considered but have not been found to be persuasive. While it is agreed that the results are unexpectedly better than those achieved with albumin, the motivation to combine the teachings of these patents is that both methods are used to inactivate viruses. Albumin is not useful for this purpose and is not taught by these patents; thus an improvement over albumin is not relevant to this combination of references. That the

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present invention is not based on virus inactivation also does not render the invention non-obvious. The motivation to combine need not be that of Applicant; the resulting method is the same, regardless of the rationale for developing it.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Janet Andres, Ph.D.

December 31, 2003


JANET ANDRES
PATENT EXAMINER